

REMARKS/ARGUMENTS

By this Amendment, claims 33 and 36 have been amended. Claims 31, 33-34 and 36-38 are pending.

Rejection of Claims under 35 U.S.C. 112, second paragraph

The Examiner states that claims 33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states further that claims 33 and 36 have improper dependency and a lack of antecedent basis for the term antibiotic. Accordingly, Applicants have amended claims 33 and 36 to correct these issues which should obviate the Examiner's rejection.

Rejection of claims under 35 U.S.C. §103(a)

Claims 31-38 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Shor et al (US Patent No. 5,424,187) and Mitchell et al. (U.S. Patent No. 6,664,239) in combination with Koskiniemi et al (Eur. Neurol. 1996). This rejection is respectfully traversed.

Neither Shor et al. nor Koskiniemi et al. suggest, teach or motivate one of ordinary skill in the art to treat Alzheimer's disease with an antibiotic. The Examiner has relied upon Mitchell et al. to show the treatment of Alzheimer's disease with antibiotics or antibiotics in combination with anti-inflammatory agents. Applicants previously attempted to remove Mitchell et al. as a reference on the basis of a Declaration Under 37 C.F.R. 1.131 from co-inventor Brain J. Balin. With that Declaration, Applicants submitted as proof of conception a letter of recommendation written by Dr. Balin. However, the Examiner stated that the Declaration was not persuasive.

The Examiner stated that the Declaration was not persuasive because it failed to state that Alzheimer's disease can be treated with an anti-microbial agent. The Examiner stated further that there is nothing in the instant claims relating to *Chlamydia pneumoniae*. Regarding the second point made by the Examiner, Applicants agree. However, lack of mention of *Chlamydia pneumoniae* in the claims is appropriate. The disease being treated is Alzheimer's disease. The fact that *Chlamydia pneumoniae* is a target for the microbial agent concerns the mechanism of

how the treatment works. It is not necessary to discuss the mechanism of a drug action in a claim. Regarding the first point, it is true that the letter attached to the Declaration failed to contain an explicit statement along the lines, "Alzheimer's Disease can be treated using an antimicrobial agent." Nevertheless it is clear from the letter that Dr. Balin indeed had a clear conception that treating Chlamydia infection would improve the symptoms of Alzheimer's disease. This can be seen from at least 4 excerpts from Dr. Balin's letter attached to his Declaration.

(1) "...recent findings in my laboratory into a potential causative agent of Alzheimer's disease has lead to a change in Jamie's thesis project."

(2) "This project has such great potential..."

(3) "Therefore the focus of his thesis project is on the role *Chlamydia Pneumoniae* plays as an infectious agent in the pathogenesis of Alzheimer's Disease."

(4) "This work has very exciting potential..."

Terms such as "great potential" and "exciting potential" show a clear concept in Dr. Balin's mind that treatment for *Chlamydia Pneumoniae* (known in the art to be accomplishable with antibiotics) would also be a treatment for Alzheimer's disease. Furthermore, his concept was not based on abstract reasoning – it was based on findings in his laboratory. Therefore, the excerpts from his letter confirm Dr. Balin's assertion, in paragraph 2 of his Declaration Under 37 CFR 1.131, that his letter showed that he had a conception of the invention.

Furthermore, prior to the earliest filing date of the Mitchell reference, Dr. Balin and co-workers had extensive data supporting their concept. This data is far in excess of anything Mitchell et al included in their patent application. Indeed, Mitchell et al merely included Alzheimer's disease in a long list of diseases in their patent application and subsequent patent.

Attached is a Second Declaration Under 37 CFR 1.131, signed by Dr. Balin and referring to a manuscript that contains the extensive data that supported the concept of the invention. The manuscript antedates the Mitchell reference's May 6, 1997 date. As indicated in paragraphs 3 and 4 of the Second Declaration, the inventors were in possession of the following data prior to

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May 6, 1997: Nineteen late-onset AD brains and 19 non-AD brains were screened for the presence of *C. pneumoniae* DNA by two PCR assays. The results showed that 17/19 AD brains were positive for *C. pneumoniae* DNA in the PCR assays and 18/19 non-AD brains were negative for *C. pneumoniae* DNA in the PCR assays. (See, e.g., pages 7-8 of the manuscript.) Also, in order to identify the area(s) and host cell types within which the *C. pneumoniae* resides in the AD brain, immunohistochemical analysis was performed with a *C. pneumoniae* MOMP-specific monoclonal antibody on tissues from affected regions of AD brains. In sections of hippocampus and temporal cortex from 10 AD brains, a consistent pattern of immunolabeling was observed. In sections of hippocampus and temporal cortex from 6 non-AD brains, no significant immunolabeling was observed. (See, e.g., page 10 of the manuscript.)

In view of the foregoing, Applicants respectfully request a withdrawal of the Examiner's rejection.

Rejection of claim under 35 U.S.C. §102(a)

Claims 31, 33, 34 and 36-38 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Mitchell et al. The Examiner states that Mitchell et al discloses the treatment of Alzheimer's disease with antibiotics or antibiotics in combination with anti-inflammatory agents. This rejection is respectfully traversed.

At the minimum, the rejection should be withdrawn in view of the two Declarations Under 37 CFR 1.131 of Dr. Balin, discussed above. Furthermore, the Mitchell et al reference is not enabling.

MPEP §2121.01 relates to the enablement requirement for references cited as prior art, and provides in pertinent part:

In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). *>The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo*

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Foundation for Medical and Education Research, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003). (Emphasis added)

Thus, to be an effective prior art reference, Mitchell et al. must be an enabling disclosure "of the desired subject matter" which includes treating Alzheimer's disease with an antibiotic. However, Mitchell et al. provides no concrete connection between *Chlamydia pneumoniae* infection and Alzheimer's disease. In fact, Alzheimer's disease is simply listed in the specification (column 30, line 52) as potentially treatable along with many other common diseases. Therefore, because Mitchell et al. shows a "mere naming or description of the subject matter" which "cannot be produced without undue experimentation" and in light of Applicant's Declarations, the rejection should be withdrawn.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

April 20, 2005

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